

# EXHIBIT 11



**From:** Globerman, Eric [ETHUS] <EGlober7@its.jnj.com>  
**Sent:** Mon, 15 Dec 2008 14:59:57 GMT  
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**Subject:** FW: Q&A transcription

Scott,

Attached is the transcript from the +M webinar. This is what will need to be submitted to Copy Review. There are a couple of time stamps that are in the middle of the presentation. This means the transcriber could not understand what was being said and we will have to fill in the blanks. Let me know if you have any questions.

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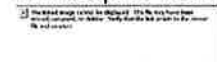
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-----Original Message-----

**From:** Christophe Remy [mailto:cremy@medvisionusa.com]  
**Sent:** Sunday, December 14, 2008 11:45 AM  
**To:** Globerman, Eric [ETHUS]  
**Subject:** Q&A transcription

Eric,  
Attached is the transcription for Dr Lucente's webinar.

**Christophe Remy**



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Dr. Lucente

Voice: Alright. Thank you Dr. Lucente.

Before we get into the Q and A session, I want to let each of you know about the commercialization plan for PROLIFT +M. This product has been FDA approved for use and we anticipate having product available for ordering the first week in January. As one of the first surgeons trained on this device, you will have the ability to start ordering this device the first week of January. The only hospitals that have access to order this device in January are those accounts that you operate in. Your local sales representative has provided us with the appropriate account information and your accounts have been activated for ordering. Wide spread commercialization will begin in February.

At this time we're gonna start some questions and we've had several questions come in on line and we'll go ahead and answer those questions before we start with the open mic and take phone line questions. The first question would be for you Dr. Lucente.

Did the change in graft properties of PROLIFT +M require you to adjust your PROLIFT technique in any way, if so where or how?

Dr. Lucente: No it really hasn't. We haven't changed our technique at all based on +M. I can say that we had made a few changes or time from the time we first started doing PROLIFT in 2004 and some of those changes, I think, I've shared with the people out there and little subtleties about, you know, the setting or the adjustment of the mesh where we tend to displace the vagina inwardly mimicking deep penetration and then deploy the mesh by removing the cannulas, so that's been a significant change, but it wasn't related to the +M. The other change is that we've gone to when the cervix is in place and preserving the uterus, especially important in vaginal lengths that aren't as long as we like so we don't remove the cervix and create vaginal foreshortening, is now instead of 1 single tacking suture to the mesh to 3 tacking sutures. I'm not sure yet if that's gonna make a difference, but one of the things we have wrestled with is uterine prolapse around or between mesh in some of our patients over time. So, there's been no real change related to +M. I would say the biggest difference in our practice pattern related to the new mesh is patient selection. Actually, I think, some of us out there have known that I was actually holding patients off for nearly a year waiting for the new mesh and these were our younger sexually active patients; the 30 year olds, 40 year olds and so on. So, I think the biggest consideration, I think, is in patient selection and making sure that the patients that are sexually active can understand what we're trying to achieve with this new mesh and have them be reassured. Based on the recent FDA release, our discussions have been a little bit longer and a little bit more detailed about sexual comfort and achieving enjoyable intercourse.

Waiting for our next question now.

Voice: Alright at this point, if anybody has a question by phone we're going to go ahead and open up those phone lines.

Operator: The floor is now open for questions. If you have a question over the phone, please press \*1 on your telephone keypad at this time. The questions will be taken in the order that they are received. Using a speaker phone, we ask that when posing your question, you pick up your handset to provide favorable sound quality. If at anytime your question has been answered, you can remove yourself from the queue by pressing #. Again, ladies and gentleman if you have a question or comment please press \*1 on your telephone keypad at this time. Please hold while we pole for questions.

Voice: Alright, while we're waiting for questions to come in by the phone line, I'm gonna go ahead. There are several that have come in on the internet. First one here says, Dr. Lucente can you describe the ideal patient for the first few cases and this might be in consideration of somebody who's potentially not using PROLIFT?

Dr. Lucente: Inevitably I would say that someone who's never use PROLIFT before that you should choose a patient that is not obese, who has not had multiple prior surgeries and ideally not sexually active and has, hopefully, some reasonable vaginal tissue quality. We want to concern ourselves with the things that we all worried about tissue healing and comfort; the 2 things that, again, have plagued us all along using an implant, erosion and discomfort. So, lets look for patients who are not going to have a wound healing problem, are not going to perhaps be exposed to dyspareunia; so, we sort of take that off our concern list and obviously anytime you're doing surgery, I don't care if its vaginal, abdominal, laparoscopic, nonobese patients are much easier. So, stack the deck in your own favor clinically and surgically and choose an easy case for yourself so that you can execute it and minimize the changes of complications. So, I'd say the patient in good overall health, not a problem with wound healing, not sexually active, nonobese and no prior surgeries and I think that would be the ideal patient to start with.

Voice: Great. There is actually another question here. It says great presentation Vince. Allen Kenny from Toronto- With less scar tissue formation, are you seeing less tissue retraction postop?

Dr. Lucente: Yes, we are. We are seeing, again, less whether you call it traction banding or scarring, we all know it, hard to, you know, sort of describe it, but we know it when we tactilely palpate the vagina and feel a contraction band or, you know, some fibrosis contraction. So, we are seeing much less of that when we examine these patients. So, I've remained significantly optimistic about what we're gonna be able to measure with these patients. Going forward, I think the thing that we need to think about in or related to a better implant is better, sort of, postoperative considerations. We're probably the only implant surgeons that are placing our target tissue on rest for prolong periods of time after our implant surgery and one of the things I've been kind of vocal about without having a lot of science to back myself up yet, although we're working on that, is looking and considering the vaginal, I guess, physiologic rehabilitation during that postoperative time frame and, of course, it's difficult to, you know, to suggest intercourse per say, but should we be exploring whether it's dilators or some other physical therapy during this time frame because I don't know of any other implant surgeon looking at re-enforcing

tissue -- 6:35 -- or what have you that utilizes such prolonged rest because again I think that's gonna be suboptimal.

Voice: Excellent. At this time operator are there any calls that have come in from the phone line?

Operator: Yes. We have a question from Dr. Barry -- 6:52 --, please go ahead.

Barry: Hey Vince how are ya buddy.

Dr. Lucente: Hey Barry how are ya.

Barry: Good. Good. Listen Vince; at this point in time are any patients at whom you would not use PROLIFT +M?

Dr. Lucente: Good question and a difficult one. I would say I would go back to PROLIFT in general. Because until we have a harder science on PROLIFT M, I wouldn't want to over sell and under deliver. I think we need to still be cautious of what we know about who are not, perhaps, ideal candidates for this. In our literature in our series points to the 3 areas that increase the likelihood of pain and that is a patient of a younger age, so just by youth along that's a risk factor. Secondly, as a patient who's had a prior pelvic surgery with a permanent material being utilized, be it suture or graft, and third category we've identified is a chronic pain disorder of any type. So, you take a patient who's 30 years of age, has had a prior surgery that used say, even Ethibon sutures and right away she has fibromyalgia or chronic migraines or some chronic pain disorder and again I'm not a pain specialist, but we all know that once those C-fibers get activated they tend to stay activated and be hypersensitive and, of course, I'm more concerned about chronic pelvic pain disorders, but we've actually seen with any chronic pain. So, I counsel those patients and I do consider them, however, relative contraindications. I have yet to come up with an absolute contraindication. The times that I may do that is someone has a prior mesh attempt and the patient already has mesh placed vaginally and it's recurred for whatever reason, I do not try to go back and we've done that, but that's more of a technical consideration. So, the long-winded answer is no real absolute contraindications. I have some relative contraindications and I counsel those patients, but I tell you that I tell you that I have done that and I have given those patients that spiel I just gave you and they said I understand you Dr. Lucente. I want the PROLIFT procedure because they've already had 1 or 2 failures and they're at the end of the rope and so I have done it, but that's my consideration, my thoughts.

Barry: Vince as you go forward from here, do you foresee any patients that you will not do +M and you would hold out and do the original polypropylene mesh procedure?

Dr. Lucente: I would say not at all. I would find it hard pressed for me to ever go back up to a middle weight mesh knowing, based on the hernia literature I've looked at and extensively reviewed the hernia literature and the force loads on those and our experience to date, to me this is a superior implant for the reasons we want it to be and I don't see

any concern that I need to go back to 100% permanent heavier or I should say, middle weight mesh. GYNEMESH was, again, a great advancement in its day, but I personally think we moved beyond that. I can't foresee myself going back to, and I don't mean to say back as backwards, but I think once I moved on to +M, I'm gonna stay there.

Voice: Great. Operator before we take more of the online questions, are there any other calls that have come in by phone?

Operator: Yes, we have another question from Douglas Greer. Please go ahead.

Douglas Greer: Hi Vince. The one question was answered and that is why would you go back to regular PROLIFT if this is superior. How far out do you have your patients now?

Dr. Lucente: First one I think we put in is August. I can't give you the hard time, but it's been a while and I have a little bit of a confession here is that I actually went off, what is that called sort of off line or-- the thing that we're allowed to do to use something-- is ULTRAPRO. I took some ULTRAPRO and jury rigged a few before I actually had the +M because I had 2 patients that were literally desperate. So, those patients went in early June or something. And again, that was my own little adventure. So far, knock wood, they have done extremely well. We do not have a single reported case of dyspareunia to date. I think we're up to like 30 cases all in all and the farthest out is from August til now. So it's early, but I have to tell you, although it's early it's extremely encouraging because, you know, you've been doing this work a long time like myself and when you examine these ladies and, you know, your fingers can tell you a lot as you begin to probe and explore the architecture and feel tactilely, you know, the distensibility, the length, the architecture and you get the good feeling that this is a much more natural and anatomical implant.

Douglas Greer: Yeah, my experience at 6 months you'll feel whether you're gonna have tension bands or not.

Dr. Lucente: Exactly, I agree.

Douglas Greer: Now, have you had the Empathy product in your hands, have you felt that; the one from Scotland?

Dr. Lucente: Which product, I'm sorry?

Douglas Greer: It's Empathy. It's a new very light-weight mesh.

Dr. Lucente: No, I have to say I've not.

Douglas Greer: They have more of a Capio device as far as how to place it, but it's also a very light-weight mesh. I was wondering to compare its characteristics.



Dr. Lucente: Yeah, ya know and I think that's a great point, you know and I think these things have to be taken, I think, in tangent together. I think the delivery system and the mesh have to be taken in composite and I'll go out to say I'm very, sort of, anti suturing and I think because it makes it much, much more difficult to actually get a sense of what I want to call the setting of the mesh, suturing creates a much greater challenge to me where I do like, sort of, the adjustability of the tension-free arm. So, although I know a lot of surgeons gravitate towards the kind of suture Capio, I personally gravitate the other because I think it's extremely hard to really get a mesh setting that's tension free. It takes some of the guess work out of it and to me our biggest enemy by far is dyspareunia. It is and now we're concentrating in doing everything possible to minimize that risk and I think staying away from sutures is another stack on that deck to stay away from pain.

Douglas Greer: But, you said you tack with 3 sutures; 2 at the apex 1 distal?

Dr. Lucente: Yeah, those again, tacking sutures that dissolve distally. Tacking sutures to the cervix, I'm not concerned about creating pain on securing the cervix to the cephalad edge. I meant, you know, securing the implant to the body.

Douglas Greer: You bet, where it contracts down and narrows.

Dr. Lucente: Yeah exactly.

Voice #2: In some of the early research that was done, one of the intents was to look at very light weight graft and with some of the early research that-- what was found was that there was some underestimation of the forces that the graft undertakes being put in place and then when it is tuned, that the fear that we had and certainly the feedback that we had from people that were looking at it from a clinical perspective was that there is such a thing as being too light weight and the graft then deforms, but also the work that Boulanger and --14:11 -- did and I know Cobb has been very interested in it from a hernia point of view is the affect of a graft that is too light weight will do from the forces of the wound healing and what would happen to it when it came to wrinkling and contracting. But, it was definitely an area that we looked at and found that those early mechanics of the graft as it's put in and through the wound healing you actually need a graft that is actually quite a bit stiff and then something that, as time goes on, has been saluted to would be very light weight thin.

Dr. Lucente: Yeah, you almost want to resist the mild contractile elements of the fibroblast during that wound healing because it's gonna create, you know, what it's trying to do naturally is obviously pull the wound together to close it and it's a natural, but undesired, wound repair process and if they don't have some biomechanical resistance of that even the natural wound healing will give us contraction.

Douglas Greer: I liked you idea of some kind of vaginal dilation, but the other side of the fear is breaking the suture line open.



Dr. Lucente: Yeah, you're absolutely right and there is the thing that we need to work out; at what point can we begin some vaginal rehabilitation and not worry about incision separation. It seems that we're a little bit more timid and reluctant than then all our other surgical counterparts because none of them are so concerned that, you know, their incisions are going to "split open". So, I think we've been a little bit overly concerned about that and that we need to think about it, but I think we need to push forward because I think it's a missed opportunity that we need to address.

Douglas Greer: We their incisions don't live in a sea of bacteria.

Dr. Lucente: Absolutely. I'm not saying it's easy, but it's something we need to push ourselves to think a little bit more about, you're right.

Voice: Alright operator, are there any other phone calls on line right now?

Operator: Yes, we have another question from Mohamed Antar. Please go ahead.

Mohamed Antar: Thank you. Hey Vince.

Dr. Lucente: Hey Mohamed.

Mohamed Antar: You know one of the challenges I still have is in the area of apical support, especially when you're dealing with the anterior compartment. Is this gonna help any?

Dr. Lucente: I would say just purely as it is now, not significantly. I think-- we've talked before, Mohamed, it that I think getting that more proximal needle; 1 at the base of the ischial spine, all the way up to the ischial spine is important and then secondly looking at, you know, either putting in a total total when we really need that apical lengthening or, again, a lot of us have talked about some modifications of the geometry ourselves. You know about the work that Dr. --16:52-- and I have been doing. You can look at the publication that was presented at --16:58-- from the McGee group making sort of a surgeon modification of a modified total. I think that's the best way to address that. I know that ETHICON is working feverishly trying to give us a new geometry to address that and I stay tuned so that would, again, save me some operative time of having to intraoperatively construct it. But as is, I don't think it's gonna give us the additionally focused support that some of these modifications and future geometries may give us.

Mohamed Antar: Thanks.

Voice: Alright. We have a question online here that says: Clinically does the mesh need to be tension differently in situ anticipating less contracture?

Dr. Lucente: Now, we thought a lot about that, you know, we didn't change our settings because it's all science to begin with and we've been getting some good results. So, we decided to just sort of continue to set things the same as we've been and see how the

chips fall and so far we haven't seen anything deleterious or adverse so we've gone with the same sort of process where we put our meshes in, they're tension free, we close the vaginal incisions all the way and every last thing we do is displace the vagina inward as far as that individual vagina will displace and then deploy the cannula on the anterior meshes and then similarly rectally and it's just as important, I think, for us to realize again that the rectum may need to distend quite significantly based on diet and fiber that enlarge bolus of fecal material could create quite a big distention in the rectum, so likewise when we deploy the posterior arms, again, we put a finger in rectally and mimic distention of the anterior rectal wall and then deploy and we continue to do that. We haven't changed anything despite the physics because I think we're really looking for more of a pain issue and something related to what other people looked at -- explain that's what we call sort of macro micro neurofiber traction. So, I haven't seen anything on a surgeon standpoint as of yet, but we're gonna continue to put a lot of our mental energy on this issue, but so far I didn't want to change too much at once because then you don't know whether you're coming or going. The only thing that we entertained that we did and then stopped was we did pack with a gauze packing an additional 24 hours. We usually pull our packs out routinely in everybody on day 1. We went to day 2, but that just became a logistical nightmare with the patients and the packing at home and what have you, so we backed off of that.

Voice: Alright. Dr. Lucente can you describe in light of the FDA mesh notification as well as your change from PROLIFT to PROLIFT +M, could you address how your informed consent has changed or if it has changed with your patients?

Dr. Lucente: Yeah, a lot of you know that I have already have had for the last several years a dedicated consent just for this procedure. It's several paragraphs and I have the patient initial each paragraph and the largest paragraph, by far, is specifically delving into this area of the mesh openly discussing the full disclosure, the lack of long-term data, the limited evidence and randomized clinical trials in layman's terms so that they can understand it and also, you know, I share with them the FDA announcement, I give them the website to go look more and I also tell them that we full comply and then some with all the FDA recommendations of the statement. So, we have increased our communication as well as our documentations along with that. I do spend some time sharing with them that, quite frankly, I believe the vast majority of those adverse events that the FDA has on file are due to surgical technique and not the material itself and that's unfortunately a factor that's very difficult to account for so the FDA is at a disadvantage to have that kind of granularity. So, I think an open, you know, honest candid discussion goes a long way and obviously in the medicolegal world we live in just to improve your documentation and I have to admit we've gotten some positive feedback from patients about that process in saying this is the most time anyone spent specifically going over the surgery and provided the most information to them. And again, part of that FDA recommendation is to provide the patient with a copy of the patient labeling provided by the manufacturer and that is available to you from ETHICON and we do that on every patient and actually document that we've done that as well.

Voice: Alright in the interest of time to keep this on track we're going to go ahead and take one last question here. The question says if a patient has had a previous vaginal erosion, are you afraid of repeating a mesh repair?

Dr. Lucente: No, I wouldn't. I guess my concern is whether you're going to put a mesh in the same spot or another compartment. So, I'm not. I think most mesh exposures, and again I use the word exposure when mesh comes back in the vaginal lumen, an erosion if mesh finds its way into the visceral lumen, so I'm gonna assume that we're really speaking about vaginal exposure. No, I'm really not. I think most often that's maybe too superficial placement and I'm not gonna be all that concerned. If I feel that a patient has poor healing properties, they're immuno compromised, diabetic, what have you then I would, again, counsel the patient that in fact since they had exposure once before the increased risk a second time, but our experience has been exposures are uncommon down to 1 to 2% when properly placed, they're easily treated, in my experience in the exposures we have from our cases they're 100% curable. I do not have a single exposure that is persistent in refractory. There is over, you know, to me it's a misbalanced discussion, an over emphasis and over concern. Exposure is not our clinical concern. Discomfort, especially with intercourse, dyspareunia is definitely speculated as the primary clinical concern and, therefore, we spend most of our clinical energies on.

Voice: Great. Thank you very much for your time this afternoon Dr. Lucente. I appreciate you joining us.

For those of you on the phone, we'd like to thank you for your participation in today's WebEx. If you have any additional questions, please do not hesitate to call or email me. As we move through the launch of this product you will be receiving further communication from myself as well as from your local sales representation and again thank you for joining us this afternoon.